DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-920/S-006

Scios Inc.
Attention: Hana B. Moran, Ph.D.
Sr. Director, Regulatory Affairs
6500 Paseo Padre Parkway
Fremont, CA 94555-3658

Dear Dr. Moran:

Please refer to your supplemental new drug application dated November 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Natrecor (nesiritide) for Injection.

We acknowledge receipt of your submission dated April 27, 2005.

This "Changes Being Effected" supplemental new drug application provides for labeling to be revised as follows:

1. Under **DOSAGE AND ADMINISTRATION/Dosing Instructions**, the second paragraph has been changed from:

   Prime the IV tubing with an infusion of 25 mL prior to connecting to the patient's vascular access port and prior to administering the bolus or starting the infusion.

   To:

   Prime the IV tubing with 5 mL of the solution for infusion prior to connecting to the patient's vascular access port and prior to administering the bolus or starting the infusion.

2. The document number and date have been updated.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the labeling submitted on April 27, 2005.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call please contact:

Mr. Russell Fortney
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

4/29/05 06:46:25 AM